IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

UNITED STATES OF AMERICA, *Plaintiff,* v. SPALITTO'S PHARMACY, L.C., *Defendant.*	Civil Action No. 4:21-cv-00600-GAF

UNOPPOSED MOTION TO ENTER CONSENT DECREE
(*With Suggestions in Support Incorporated*)

The United States of America moves the Court to execute the parties' proposed consent decree and enter final judgment in this case.

On August 16, 2021, pursuant to the injunctive relief provisions of the Controlled Substances Act, 21 U.S.C. § 882(a), the United States filed a civil complaint for a permanent injunction against Spalitto's Pharmacy, L.C., alleging violations of the Controlled Substances Act, 21 U.S.C. §§ 841(a)(1), 842(a)(1). The Complaint alleges that Spalitto's Pharmacy violated the Controlled Substances Act by dispensing controlled substances outside the usual course of the professional practice of pharmacy and by dispensing controlled substances in violation of 21 U.S.C. § 829 and the Controlled Substances Act's implementing regulations. As described in the attached Joint Stipulation, the parties wish to resolve this matter through a proposed consent decree, in a form to be submitted to chambers. For the reasons summarized below, the Court should execute the consent decree and enter final judgment in this case.

Legal Standard

There is a "strong federal policy favoring the approval and enforcement of consent decrees." *SEC v. Citigroup Global Mkts., Inc.*, 752 F.3d 285, 293–94 (2d Cir. 2014) (citation omitted). "Although the law favors settlements, federal courts in adopting consent decrees are

not mere 'recorders of contracts' from whom parties can purchase injunctions." *Angela R. by Hesselbein v. Clinton*, 999 F.2d 320, 324 (8th Cir. 1993) (quoting *Local Number 93, Int'l Ass'n of Firefighters v. City of Cleveland*, 478 U.S. 501, 525 (1986)). "Consent decrees should: spring from—and serve to resolve—a dispute within the court's subject-matter jurisdiction; come within the general scope of the case from the pleadings; and, further the objectives of the law on which the complaint was based." *E.E.O.C. v. Prod. Fabricators, Inc.*, 666 F.3d 1170, 1172 (8th Cir. 2012) (citing *Local 93, Int'l Ass'n of Firefighters*, 478 U.S. at 525). "A consent decree is a judicial act. Thus, before entering such a decree, the Court must ensure that it does not 'put the court's sanction on and power behind a decree that violates Constitution, statute, or jurisprudence.' " *Missouri v. Westinghouse Elec., LLC*, 487 F. Supp. 2d 1076, 1088 (E.D. Mo. 2007) (quoting *United States v. City of Miami*, 664 F.2d 435, 441 (5th Cir. 1981)).

"When reviewing a proposed consent decree, the trial court is to review the settlement for fairness, reasonableness, and adequacy." *United States v. Metro. St. Louis Sewer Dist. (MSD)*, 952 F.2d 1040, 1044 (8th Cir. 1992). A consent decree must be "consisten[t] with the governing statute." *United States v. Union Elec. Co.*, 132 F.3d 422, 430 (8th Cir. 1997). Whether a consent decree is "fair and reasonable" turns on "(1) the basic legality of the decree; (2) whether the terms of the decree, including its enforcement mechanism, are clear; (3) whether the consent decree reflects a resolution of the actual claims in the complaint; and (4) whether the consent decree is tainted by improper collusion or corruption of some kind." *Citigroup*, 752 F.3d at 294–95 (citations omitted). *See also Dalton v. Barrett*, No. 2:17-CV-04057-NKL, 2020 WL 420833, at *3 (W.D. Mo. Jan. 27, 2020) (citations omitted). "The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is

within the reaches of the public interest." *United States v. Bechtel Corp.*, 648 F.3d 660, 666 (9th Cir. 1981).

1. The Court has subject-matter jurisdiction over the dispute

Spalitto's Pharmacy admitted the facts necessary to establish subject-matter jurisdiction in the Joint Stipulation. ECF No. 2, ¶¶2, 9.

Spalitto's Pharmacy, L.C. is a Missouri Limited Liability Company operating a retail pharmacy in Kansas City, Missouri, within Jackson County. Compl. ¶9, ECF No. 1. Spalitto's Pharmacy engaged in the conduct described in this Complaint in the Western District of Missouri. Section 882(a) of Title 21, United States Code, provides the United States a remedy to enjoin Spalitto's Pharmacy to stop. Compl. ¶¶1–6.

2. The proposed consent decree is within the scope of the Complaint

Under 21 U.S.C. § 882(a), this Court has jurisdiction to enjoin violations of the Controlled Substances Act. The Complaint seeks a permanent injunction under 21 U.S.C. § 882(a) prohibiting Spalitto's Pharmacy from dispensing any controlled substance without verifying, either manually or through the implementation *and review* of a software or other automated program, that the prescription for the controlled substance contains a valid DEA registration number for the prescribing practitioner. The proposed consent decree would enter a substantially similar, clearly defined permanent injunction. The proposed consent decree prohibits Spalitto's Pharmacy from dispensing, 21 U.S.C. § 802(10), any controlled substance, 21 U.S.C. § 802(6), pursuant to a prescription without verifying that the prescription contains a valid DEA registration number for the prescribing practitioner, 21 U.S.C. § 802(21).

3. The proposed consent decree furthers the objectives of the Controlled Substances Act and does not violate the Constitution, a statute, or jurisprudence

A proposed consent decree with the government is legal "so long as it is within the Court's authority to enter the decree and within the Plaintiff's authority to enforce it." *United States v. International Business Machines Corp.*, No. 14–cv–936, 2014 WL 3057960, at *1 (S.D.N.Y. July 7, 2014) (citing *Benjamin v. Jacobson*, 172 F.3d 144, 158 (2d Cir. 1999)). The Court has subject-matter jurisdiction to enter the proposed consent decree and require Spalitto's Pharmacy to verify that the controlled substances it dispenses are pursuant to prescriptions that contain valid DEA registration numbers. 21 U.S.C. §§ 882(a), 842(a)(1) & 841(a)(1).

Section 882(a)(1) of Title 21, United States Code, provides for injunctive relief to remedy violations of the Controlled Substances Act. 21 U.S.C. § 882(a) (providing that a district court shall have jurisdiction to enjoin violations of Subchapter I of Chapter 13 of Title 21). Here, the government alleges Spalitto's Pharmacy has violated at least two provisions of the Controlled Substances Act: 21 U.S.C. § 842(a)(1) (Improper Dispensing) and 21 U.S.C. § 841(a)(1) (Knowingly Dispensing Controlled Substances). Compl. ¶¶1–5 (summarizing violations), ¶¶11–31 (setting forth violations found in the Gaston forged prescriptions), ¶¶32–40 (setting forth violations found in the prescriptions purporting to be written by A.D.). Under 21 U.S.C. § 842(a)(1), it is unlawful for any DEA registrant, including a retail pharmacy, to dispense a controlled substance without a valid prescription. *United States v. Moore*, 423 U.S. 122, 341–42, n.11 (1975). A prescription is not valid unless it complies with the CSA and the relevant CSA regulations. *See, e.g.*, *Heartland Pharmacy, Inc. v. Rosen*, 2021 WL 650350, at *3, n.4 (S.D. Fl. 2021) ("Because it is unlawful to dispense controlled substances in violation of 21 U.S.C. § 842(a)(1), whose scope is defined in part by 21 C.F.R. §§ 1306.04(a), 1306.06, a violation of these regulations constitutes a violation of federal law").

The Complaint alleges that Spalitto's Pharmacy dispensed controlled substances pursuant to forged and facially invalid prescriptions, in violation of DEA statutory and regulatory requirements. Such requirements include that a prescription be issued by an individual practitioner who is authorized to prescribe controlled substances under the laws of the state in which he or she is licensed to practice and is either registered with DEA or exempt from registration. 21 C.F.R. § 1306.03(a). The prescription also "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.03(a). If the prescription does not comply with the requirements of § 1306.04(a), then the practitioner who issues the invalid prescription and the pharmacist who fills the invalid prescription both violate the law. 21 C.F.R. § 1306.04(a) (pharmacists have a corresponding responsibility to ensure that the prescriptions that they fill comply with § 1306.04(a)); *United States v. Lovern*, 590 F.3d 1095, 1102 (10th Cir. 2009) (Gorsuch, J.) (CSA "regulations expressly place a duty on pharmacists not to knowingly fill prescriptions issued outside the usual course of medical practice. *See* 21 C.F.R. § 1306.04(a)."). Where, as here, a pharmacy is presented with prescriptions that raise red flags, Compl. ¶¶1–5, ¶¶11–31, ¶¶32–40, the pharmacy must resolve the red flags and document that resolution. *Pharmacy Doctors Enterprises Inc. v. Drug Enforcement Administration*, 789 Fed. Appx. 724, 731 (11th Cir. 2019). The government alleges Spalitto's Pharmacy was presented with prescriptions that contained numerous (likely unresolvable) red flags (Compl. ¶¶1–5), did not even attempt to resolve the red flags, and, nonetheless, dispensed controlled substances, which were almost always highly addictive narcotics.

The government further alleges the actions of Spalitto's Pharmacy in disregarding were sufficiently egregious to violate 21 U.S.C. § 841(a)(1), which prohibits knowingly or intentionally distributing a controlled substance. *See, e.g.*, *United States v. Otuonye*, 995 F.3d 1191, 1211–12 (10th Cir. 2021) (upholding pharmacist's criminal conviction under 21 U.S.C. § 841(a)(1) for dispensing controlled substances outside the usual course of professional practice and without a legitimate medical purpose where the evidence was sufficient to find that the pharmacist was deliberately blind because red flags, including prescription "dosages, pill quantities, and dangerous drug combinations" "should have alerted [the pharmacist] that the prescriptions did not have a legitimate medical purpose and were prescribed outside the usual course of professional medical practice) (citing *United States v. Santos*, 553 U.S. 507, 521 (2008) (opinion of Scalia, J.) ("[K]nowledge must almost always be proved[ ] by circumstantial evidence.")).

The Complaint also alleges specific instances of Spalitto's Pharmacy's deliberate indifference to filling invalid prescriptions. Since April 2007, the U.S. Department of Justice, Drug Enforcement Administration has made available to DEA registrants, including Spalitto's Pharmacy, a free online tool to validate DEA registration numbers. Compl. ¶30. In September 2019, Spalitto's Pharmacy was educated by DEA about this free option, as well as commercial options. *Id.* However, Spalitto's Pharmacy ignored the ability to freely validate DEA registration numbers, declined to change its practices, and continued to fill invalid prescriptions presenting significant red flags. Compl. ¶¶3, 26–40. The pharmacy also failed to act where the prescription drug monitoring program revealed that only Defendant was filling prescriptions attributable to either of two physicians. Compl. ¶¶2–3. This fact is particularly concerning, given that approximately one dozen different individuals all presented Spalitto's Pharmacy with

substantially similar prescriptions from the same physician, A.D. Compl. ¶3. Only after this action was imminent did Spalitto's Pharmacy purchase commercial software to validate prescriptions. But simply purchasing software to automate the validation process is not enough. *See* Compl. ¶30 (alleging that Spalitto's Pharmacy has ignored the DEA's freely available validation process since 2007). Spalitto's Pharmacy has an obligation to stop ignoring the validation information available to it and *verify* that for each prescription containing an invalid DEA registration number, Spalitto's Pharmacy does not dispense any controlled substances. *See* 21 U.S.C. §§ 841(a)(1), 842(a)(1).

4. The proposed consent decree is fair, reasonable, and adequate

In this case, the primary focus of this Court's review should be on ensuring the procedural propriety of the proposed consent decree. Here, before the government filed this action, it provided Spalitto's Pharmacy with a copy of the proposed consent decree and stipulation. Spalitto's Pharmacy agreed to the entry of the proposed consent decree and in executing the Joint Stipulation expressly acknowledged that it entered into the agreement "freely, and without coercion," and that it "read the provisions of the proposed Consent Decree, had sufficient time to consider its ramifications, [and] understands [it]." Jt. Stipulation ¶¶2, 8. In signing the Joint Stipulation, Spalitto's Pharmacy also agreed to waive service of the Summons and Complaint. Jt. Stipulation ¶1.

Moreover, the terms of the proposed consent decree are fair, reasonable, and adequate. The terms of the consent decree are clear and dispositive of all claims in the government's Complaint. The decree is straightforward, and the injunction contains one core provision that prevents Spalitto's Pharmacy and its agents from dispensing any controlled substance without verifying that the prescription contains a valid DEA registration number for the prescribing

practitioner, 21 U.S.C. § 802(21). This Court has authority to issue an injunction under 21 U.S.C. §§ 882(a)(1), 842(a)(1) & 841(a)(1) with substantially similar terms as the proposed consent decree.

Finally, the proposed consent decree is not "tainted by improper collusion or corruption[,]" and nothing suggests that the public interest would be disserved by entry of the proposed consent decree. *See Citigroup*, 752 F.3d at 295. The proposed consent decree orders Spalitto's Pharmacy to verify the validity of the DEA registration numbers on prescriptions. Absent the consent decree, the government could obtain similar relief under the Controlled Substances Act via a permanent injunction. *See* 21 U.S.C. § 882(a). There is no basis to conclude that the consent decree would harm the public. The consent decree effects a statutory right of the government to protect the public by stopping diversion of controlled substances. The government's exercise of that right is particularly appropriate where, as here, the defendant pharmacy's conduct resulted in the unlawful dispensing and use of dangerous and highly addictive narcotics. Additionally, the consent decree properly resolves the case by providing the Court continuing jurisdiction to monitor Spalitto's Pharmacy's compliance. *See E.E.O.C. v. Prod. Fabricators, Inc.*, 666 F.3d 1170, 1173 (8th Cir. 2012) ("Continuing jurisdiction is the norm (and often the motivation) for consent decrees."). In sum, the proposed consent decree should be approved as fair, reasonable, and adequate.

Conclusion

WHEREFORE, Plaintiff the United States of America moves the Court to execute the parties' proposed consent decree and enter final judgment in this case.

Date: August 18, 2021

Respectfully submitted,

Teresa A. Moore
Acting United States Attorney

By: ***/s/ Alan T. Simpson***

Alan T. Simpson, MO Bar No. 65183
Assistant United States Attorney
Email: alan.simpson@usdoj.gov
Charles Evans Whittaker Courthouse
400 East Ninth Street, Room 5510
Kansas City, Missouri 64106
Telephone: (816) 426-3130
Facsimile: (816) 426-3165
ATTORNEY FOR THE
UNITED STATES OF AMERICA